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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,459	05/02/2005	Curtis C. Harris	63139(47992)	3076
45142 7590 07/03/2007 BERENATO, WHITE & STAVISH, LLC 6550 ROCK SPRING DR. SUITE 240 BETHESDA, MD 20817			EXAMINER SCHLAPKOHL, WALTER	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 07/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,459	Applicant(s) HARRIS ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>WHS</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 3-5, 9-16, 20-24 and 28-29, drawn to a method for determining whether a candidate cell is a *small cell lung cancer (SCLC)* neuroendocrine tumor cell, comprising determining the profile of expression of one or one combination of genes selected from C5, CPE, GRIA2, RIMS2, ORC4L, CSF2RB, GGH, NPAT, NR3C1, P311, PRKAA2, PTK6, APRT, ARF4L, ARHGDIA, ARL7, ATP6F, CDC20, CDC34, CLDN11, COMT, CSTF1, DDX28, DHCR7, ERP70, FEN1, GCN1L1, GNB1, GUK1, HDAC7A, ITPA, JUP, KIAA0469, KRT5, PDAP1, PGAM1, PHB, POLA2, POLD2, POLE3, PYCR1, SIP2-28, SIVA, SURF1, TADA3L, TK1, TYMSTR and VATI and a microarray comprising the same one or one combination of genes.

Group II, claim(s) 4-6, 9-11, 13-14, 17-18, 20-21, 25-26 and 28-29, drawn to a method for determining whether a candidate cell is a *large cell neuroendocrine carcinoma (LCNEC)* neuroendocrine tumor cell, comprising determining the profile of expression of one or one combination of genes selected from C5, CPE, GRIA2, RIMS2, ORC4L, CSF2RB, GGH, NPAT, NR3C1, P311, PRKAA2, PTK6, APRT, ARF4L, ARHGDIA, ARL7, ATP6F, CDC20, CDC34, CLDN11, COMT, CSTF1, DDX28, DHCR7, ERP70, FEN1, GCN1L1, GNB1, GUK1, HDAC7A, ITPA, JUP, KIAA0469, KRT5, PDAP1, PGAM1, PHB, POLA2, POLD2, POLE3, PYCR1, SIP2-28, SIVA, SURF1, TADA3L, TK1, TYMSTR and VATI

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and a microarray comprising the same one or one combination of genes.

Group III, claim(s) 4-5, 7, 9-11, 13-14, 19-21, 27-29, drawn to a method for determining whether a candidate cell is a *typical carcinoid (TC)* neuroendocrine tumor cell, comprising determining the profile of expression of one or one combination of genes selected from C5, CPE, GRIA2, RIMS2, ORC4L, CSF2RB, GGH, NPAT, NR3C1, P311, PRKAA2, PTK6, APRT, ARF4L, ARHGDIA, ARL7, ATP6F, CDC20, CDC34, CLDN11, COMT, CSTF1, DDX28, DHCR7, ERP70, FEN1, GCN1L1, GNB1, GUK1, HDAC7A, ITPA, JUP, KIAA0469, KRT5, PDAP1, PGAM1, PHB, POLA2, POLD2, POLE3, PYCR1, SIP2-28, SIVA, SURF1, TADA3L, TK1, TYMSTR and VATI and a microarray comprising the same one or one combination of genes.

Group IV, claim(s) 4-5, 8-11, 13-14, 20-21 and 28-29, drawn to a method for determining whether a candidate cell is an *atypical carcinoid (AC)* neuroendocrine tumor cell, comprising determining the profile of expression of one or one combination of genes selected from C5, CPE, GRIA2, RIMS2, ORC4L, CSF2RB, GGH, NPAT, NR3C1, P311, PRKAA2, PTK6, APRT, ARF4L, ARHGDIA, ARL7, ATP6F, CDC20, CDC34, CLDN11, COMT, CSTF1, DDX28, DHCR7, ERP70, FEN1, GCN1L1, GNB1, GUK1, HDAC7A, ITPA, JUP, KIAA0469, KRT5, PDAP1, PGAM1, PHB, POLA2, POLD2, POLE3, PYCR1, SIP2-28, SIVA, SURF1, TADA3L, TK1, TYMSTR and VATI and a microarray comprising the same one or one combination of genes.

Groups I-IV are comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes which do not render each other obvious and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene or one specific combination of genes to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention.

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This is not an election of species because the genes are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct types of products and methods, followed by an election of a single invention drawn to one or one combination of sequence(s) within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the putative special technical feature of the Group I invention is the gene or combination of genes which can distinguish a *small cell lung cancer (SCLC)* neuroendocrine tumor cell from other neuroendocrine tumor cells; this putative special technical feature is not present in the other Groups. The putative

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special technical feature of the Group II invention is the gene or combination of genes which can distinguish a *large cell neuroendocrine carcinoma (LCNEC)* neuroendocrine tumor cell from other neuroendocrine tumor cells; this putative special technical feature is not present in the other Groups. The putative special technical feature of the Group III invention is the gene or combination of genes which can distinguish a *typical carcinoid (TC)* neuroendocrine tumor cell from other neuroendocrine tumor cells; this putative special technical feature is not present in the other Groups. The putative special technical feature of the Group IV invention is the gene or combination of genes which can distinguish an *atypical carcinoid (TC)* neuroendocrine tumor cell from other neuroendocrine tumor cells; this putative special technical feature is not present in the other Groups.

Claims 1-2 link(s) inventions I-IV. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-2. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall be** withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be

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rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative.

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NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

June 17, 2007


DAVID GUZO
PRIMARY EXAMINER